TCTAP A-057

Three-Year Clinical Outcome Comparison Between Everolimus-Versus Zotarolimus-Eluting Stents in All-Comers and Diabetics

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BACKGROUND The aim of the study was to investigate 3-year major clinical outcomes in patients(pts) with different type of lesions treated with the zotarolimus-eluting stent (ZES) and everolimus-eluting stent (EES) in a series of Korean population in real-world clinical practice.

METHODS A total of 1477 consecutive pts who underwent percutaneous coronary intervention (PCI) with ZES or SES from April 2003 to July 2011 were enrolled. We analyzed the overall 3-year clinical outcomes with logistic regression, and according to left main lesion, bifurcation, small vessel lesion (<2.25mm), calcification, ostial lesion and diffuse long lesion (>3cm) after propensity score matching. Further, subgroup analysis was performed for diabetics.

RESULTS In overall study population after the baseline adjustment, there were no difference between two groups, with regard to total death (EES vs. ZES, OR 0.932, 95%CI0.432-2.009, p=0.857)and cardiac death (OR0.800, 95% CI 0.314-2.042, p=0.641), for myocardial infarction (OR 1.426, 95% CI0.662-3.076, p=0.365), repeated revascularization (OR 0.992, 95% CI 0.667-1.474,p=0.967), and stent thrombosis (OR 1.212, 95% CI0.400-3.671, p=0.734). However, in *diabetic subgroup analysis*, there was significant reduction of repeated revascularization in EES versus ZES (OR 0.474, 95% CI 0.232-0.971, p=0.041), and in bifurcation lesion (OR 0.245, 95% CI 0.070-0.865, p=0.029), and in calcified lesion (OR 0.211, 95% CI 0.054-0.834, p=0.026). There were no significant differences in total death, cardiac death, MI, and stent thrombosis between EES and ZES in diabetics.

CONCLUSION ZES and EES showed similar safety and efficacy during 3-year follow-up in patients with different type of lesions in all comer bases. However, in diabetic patients, EES was associated with lower incidence of repeated revascularization rate compared to ZES, especially in patients with bifurcation or calcified lesions.

TCTAP A-058

The Changes and Clinical Outcomes of Peri-Contrast Staining (PSS) in First Generation DES Era to Second Generation DES Era

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BACKGROUND Several studies showed peri-contrast staining (PSS) after DES deployment is associated with target-lesion revascularization (TLR) and very late stent thrombosis. However, the changes of PSS after first generation DES to second generation DES are unclear, so we retrospectively compare the clinical outcomes.

METHODS This study consisted of de novo 5154 lesions in 4155 patients that were treated with first generation DES (defined as sirolimus-eluting stent and paclitaxel-eluting stent) or second generation DES (defined as zotarolimus-eluting stent, everolimus-eluting stent, and biolimus-eluting stent). They were evaluated by follow-up angiography within 12 months after stent implantation, from April 2007 to December 2012. We divided into PSS of first generation DES group and PSS of second generation DES group and compared the two groups in clinical and angiographical outcomes.

RESULTS We had obtained 4400 lesions follow-up angiography. (85.4%) Total late acquired PSS was observed in 90 lesions (2.0%), of which 17 lesions was observed in the second generation DES. Baseline clinical and angiographic characteristics were similar between the two groups. (N.S.) The rate of PSS was higher in first generation DES group. (3.2% vs. 0.9%, p<0.0001) Smooth-contour PSS was highest of first generation DES group and mono-focal PSS was highest of second generation DES group. (smooth contour:37.9% vs. 16.7%, mono-focal:34.5% vs. 61.1%, p=0.03) There was no significant difference in target lesion revascularization (TLR) and stent thrombosis (ST) between two groups, (N.S.) but cumulative incidence of TLR and ST in smooth contour PSS was higher than in non-smooth contour PSS group. (57.1% versus 21.2 %, p=0.018 and 14.3% versus 0%, p=0.025).

CONCLUSION The occurrence of PSS decreases in second generation DES era. Smooth contour PSS was frequently observed in the first generation DES and appeared to be associated with TLR and ST.

TCTAP A-059

Comparison of Drug-Eluting Balloon First and then Bare Metal Stent with Drug-Eluting Stent for Treatment of De Novo Lesions (DEB First): A Randomized Controlled Single Center Clinical Trial

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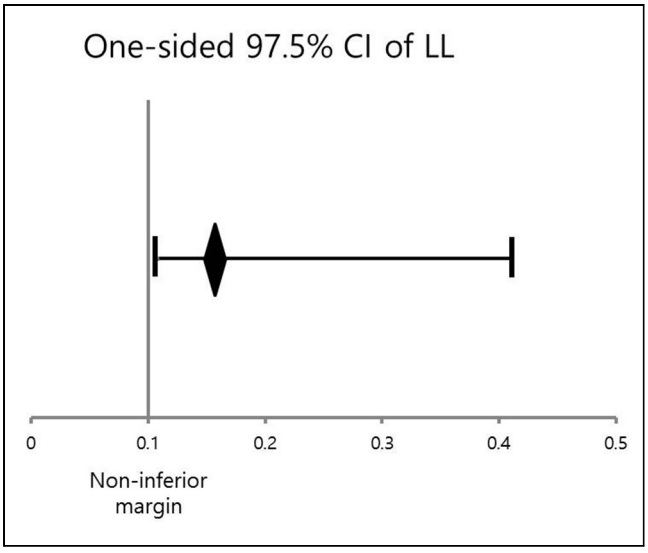
BACKGROUND The use of a drug-eluting balloon (DEB) for the treatment of de novo non-small vessel coronary artery diseases (CAD) remains to be evaluated. A previous trial which compared a bare metal stent mounted on a DEB to a sirolimus-eluting stent failed to meet the prespecified non-inferiority criteria and showed unexpected increase of myocardial infarction (MI). The stent struts of a BMS pre-mounted on a DEB might prevent an adequate delivery of the drug to the vessel wall. Therefore, we evaluated the efficacy of a sequential DEB and BMS application for treating de novo coronary lesion in comparison to a zotarolimus-eluting stent (ZES) in the present study.

METHODS The DEB First study is a prospective, randomized, open-label study. We designed it to demonstrate the non-inferiority of a DEB (Sequent®Please, B. Braun) first followed by a BMS (Coroflex® Blue, B. Braun) (DEB-BMS)compared with a ZES (Resolute Integrity™, Boston Scientific).We used a longer DEB first by 5 mm to treat the full length of a lesion than a BMS to dilate residual stenosis or dissection flap after DEB. Eligible lesion were de novo coronary artery diseases in patients with stable angina, unstable angina or non-ST segment elevation myocardial infarction. The primary endpoint of the study is in-segment late loss (LL) at 9 months measured by quantitative coronary angiography. Secondary endpoints include other angiographic finding sand clinical outcomes such as procedural success, all cause death, MI, target vessel revascularization, target lesion revascularization, and stent thrombosis.

RESULTS A total of 180 patients were enrolled in the present study. Among 90 patients randomized to DEB-BMS, 2 patients received ZES due to DEB delivery failure. There was no procedural or angiographic failure in the both groups. Mean procedure time ± SD was 58.6±23.1 vs 55.1±18.5 in DEB-BMS vs ZES (minutes, p=0.263). Stent length was 17.1±4.3 mm vs 22.2±6.4mm (p<0.001) and post-PCI minimal lesion diameter was 2.50±0.44 mm vs 2.61±0.42mm (p=0.097). There was one clinical follow-up loss in DEB-BMS at 9 months. Death occurred in a patient (1.1%) in DEB-BMS (non-cardiac) and in two patients (2.2%) in ZES (cardiac). There was no myocardial infarction in the both groups. Target lesion revascularization was done in 6 patients (6.7%) in DEB-BMS and in 2 patients (2.2%) with ZES. Nine month follow-up angiography was done in 75 patients with DEB-BMS and 72 patients with ZES. Late loss was 0.52±0.44 in DEB-BMS vs. 0.26±0.36 in ZES (p<0.001). One-sided 97.5% confidence interval of the late loss difference was 0.11 - 0.41 (p=0.990).



CONCLUSION The DEB-BMS strategy was inferior to ZES in terms of late loss at 9 months. However, we did not find increase of death or MI in contrast to the previous study, although sample size was small. Considering early re-endothelialization and no residual polymer of DEB-BMS strategy, we think that it could be a feasible alternative treatment option of de novo coronary artery lesions.

TCTAP A-060

Two-Year Results Comparing Cobalt-Chromium XIENCE V and Platinum-Chromium PROMUS Element Everolimus-Eluting Stents

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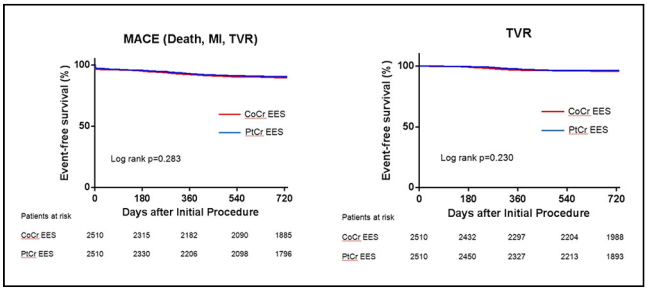
BACKGROUND It remains unclear whether there are differences in the safety and efficacy outcomes between Cobalt Chronium (CoCr-EES) and Platinum Chronium everolimus-eluting stents (PtCr-EES).

METHODS From the Interventional Cardiology Research In-Cooperation Society-Drug-Eluting Stents Registry, we identified 6065 consecutive patients who received CoCr-EES (3080 patients) and PtCr-EES (2985 patients). We compared major adverse cardiac events (MACE) which was defined using a composite measure consisting of death, nonfatal myocardial infarction, or target vessel revascularization (TVR) with the use of propensity-score matching in the overall cohort according to type of stents.

RESULTS At 2-years of clinical follow-up, the 2 study groups (n=2510 for each propensity matched group) did not differ significantly in crude risk of the MACE (12.0% for CoCr-EES versus 11.6% for PtCr-EES; HR,0.954; 95% CI, 0.81 - 1.13, p=0.581).There was also no differences between the stent groups in the risks of the individual component of death (HR, 1.083; 95% CI, 0.786 - 1.492, p=0.624), MI (HR, 0.972; 95% CI, 0.770 -1.228, p=0.812), and TVR (HR, 0.798;95% CI, 0.598 - 1.065, p=0.125). The risk of cerebrovascular event (HR, 0.914; 95% CI, 0.566 - 1.477, p=0.714) and definite stent thrombosis (HR, 1.000; 95% CI, 0.290 - 3.454, p=1.000) were also similar between the two groups.

CONCLUSION The use of CoCr-EES and PtCr-EES showed similar rates of safety and efficacy outcomes with regard to death, MI, stent thrombosis and TVR.



Hazard ratios of the clinical outcomes following the use of PtCr EES compared with CoCr EES

Outcome	Event number/rate (%)* at the 2-year follow-up examination: CoCr EES (n = 2510)	PtCr EES (n = 2510)	Hazard ratio (95% CI)	p value
Death, MI, or TVR	301 (12.0)	292 (11.6)	0.954 (0.808–1.127)	0.581
Death	74 (2.9)	82 (3.3)	1.083 (0.786–1.492)	0.624
Cardiac death	43 (1.7)	56 (2.2)	1.262 (0.842–1.892)	0.260
Non-cardiac death	31 (1.2)	26 (1.0)	0.833 (0.490–1.417)	0.501
MI	149 (5.9)	143 (5.7)	0.972 (0.770–1.228)	0.812
Spontaneous MI	21 (0.8)	26 (1.0)	1.250 (0.694–2.250)	0.457
Cerebrovascular event	37 (1.5)	33 (1.3)	0.914 (0.566–1.477)	0.714
Target vessel revascularization	109 (4.3)	92 (3.7)	0.798 (0.598–1.065)	0.125
Target lesion revascularization	85 (3.4)	63 (2.5)	0.707 (0.505–0.990)	0.044
Definite Stent thrombosis	6 (0.2)	5 (0.2)	1.000 (0.290–3.454)	1.000

TCTAP A-061

Long-Term Clinical Outcomes of Multiple Overlapping (≥60mm) Drug-Eluting Stent Implantation

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BACKGROUND There are limited data regarding the clinical outcomes of very long stent implantations, particularly the use of second generation drug-eluting stents (DES).

METHODS From the IRIS-DES Registry, we identified 406 patients who were treated for coronary stenosis using ≥ 60 mm of overlapping drug-eluting stents. Of these, 269 and 137 patients were treated using cobalt chromium everolimus eluting stent (CoCr-EES) and platinum chromium everolimus-eluting stents (PtCr-EES), respectively. Major adverse cardiac events (MACE) were defined using a composite measure consisting of death, myocardial infarction (MI; periprocedural or spontaneous), or target vessel revascularization (TVR).

RESULTS Per target lesion, the average stent number was 2.7 ± 0.7 and the average stent length was 76.3 ± 14.8 mm. On 2-year clinical follow-up, the rate of MACE, death, spontaneous MI, TVR, and stent thrombosis (definite or probable stent thrombosis) were 31.8%, 4.4%, 2.0%, 7.1%, and 0.5%, respectively. Although 88patients (21.2%) suffered from periprocedural MI, this was not independently associated with death, spontaneous MI, or TVR (hazard ratio [HR], 1.097; 95% confidence interval [CI] 0.58-2.08, p= 0.775). In addition, there were no statistical differences between CoCr-EES and PtCr-EES implantation in terms of the adjusted risks of MACE (HR, 1.223;95% CI 0.82-1.82, p = 0.321) as well as its individual components (death; HR, 0.846; 95% CI 0.311-2.305, p = 0.744, MI; HR, 1.101; 95% CI 0.686-1.768, p = 0.690, TVR; HR, 1.854; 95% CI 0.895-3.841, p = 0.097).

CONCLUSION When treating diffuse coronary stenosis, multiple overlapping stent implantations using second generation DES appear to be equally safe and effective. Although periprocedural MI frequently occurred, it was not associated with an increase in long-term adverse clinical outcomes.